UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

MARLON BOWLES	)	
	)	
Plaintiff,	)	
	)	
vs.	)	Cause No: 1:20-cv-07413
	)	
ABBVIE INC.,	)	
	)	
	)	
Defendant.	)	

PLAINTIFF'S SECOND AMENDED COMPLAINT AND JURY DEMAND

Marlon Bowles ("Plaintiff"), domiciled in Tarrant County, Texas, by and through the undersigned counsel, Ellen Presby, Van Wey, Presby & Williams PLLC and the Law Office of Keith Altman, hereby sues AbbVie Inc., ("Defendant") and alleges as follows:

INTRODUCTION

1. This case involves the prescription drug ADALIMUMAB, commonly known as HUMIRA ("HUMIRA"), which is manufactured, sold, distributed, marketed, and promoted by AbbVie Inc. ("Defendant"), as a treatment for multiple medical conditions including psoriatic arthritis since 2003.
2. In 2017, the FDA issued a Form 483 Inspection Citation to Defendant for underreporting death complaints regarding HUMIRA. Defendant misrepresented that HUMIRA is a safe and effective treatment for psoriatic arthritis since 2005 when in fact this medication causes serious medical problems including renal failure and interstitial lung disease.
3. Defendant engaged in an aggressive, direct-to-consumer and physician marketing and advertising campaign for HUMIRA. Further, AbbVie, Inc. did not warn consumers about the

risks of developing interstitial lung disease and/or renal failure from the use of HUMIRA.

4. As a result, Plaintiff, through his medical doctor, in early 2018 used a series of HUMIRA injections to treat his psoriatic arthritis, which resulted in his developing renal failure and interstitial lung disease.

5. Since the beginning of the release of HUMIRA Defendant AbbVie, Inc. has listed under Adverse Reactions serious infections including upper respiratory tract infections and pneumonia. However, they have failed to warn that HUMIRA can cause and/or exacerbate interstitial lung disease (hereinafter "ILD"). Research has shown a strong link between HUMIRA and ILD.[1] Indeed, case studies and reports worldwide indicate a long history of problems with HUMIRA causing or exacerbating ILD. In 2013 AmJ reported a case study of 122 cases in which interstitial lung disease was induced or exacerbated by TNF-targeted therapies. In 2014 Abstract in Jornal Brasileiro de Pneumologia entitled *Adalimumab-induced acute interstitial lung disease in a patient with rheumatoid arthritis* reported a case study of a 62-year-old patient with rheumatoid arthritis who developed ILD after being prescribed HUMIRA. The case clearly demonstrated evidence of an association between ILD and the use of the Anti-TNF drug HUMIRA. Defendant did not adequately research this link or warn consumers of this risk. Defendant refuses to acknowledge the dangerous connection between HUMIRA and interstitial lung disease.

[1] *See e.g.*, Dias, Olívia Meira et al. "Adalimumab-induced acute interstitial lung disease in a patient with rheumatoid arthritis." *Jornal brasileiro de pneumologia : publicacao oficial da Sociedade Brasileira de Pneumologia e Tisilogia* vol. 40,1 (2014): 77-81. doi:10.1590/S1806-37132014000100012; Alaee, Seema, and Quentin Jones. "Case of drug-induced interstitial lung disease secondary to adalimumab." *BMJ case reports* vol. 2018 bcr2018224375. 15 May. 2018, doi:10.1136/bcr-2018-224375. *Adalimumab (Humira) induced acute lung injury.* AmJ Case Rep 2013;14:77-81 and *Interstitial lung disease induced or exacerbated by TNF-targeted therapies: analysis of 122 cases.* Semin Arthritis Rheum 2011; 41:256-64.:10.1016.

6. Research and case studies have shown a strong link between HUMIRA and renal failure.[2] In 2009 the Oxford Journal University Press published a case study of a patient that developed reversible proteinuria after HUMIRA discontinuation. The patient had been on HUMIRA two weeks. HUMIRA was discontinued and the renal failure resolved. In 2013 the Nephrology Journal reported on a case study involving HUMIRA therapy exacerbates IgA Glomerulonephritis Acute Renal Injury and Induces Lupus Autoantibodies in a Psoriasis Patient. After 18 months of treatment with HUMIRA the individual developed nephritis and renal failure. He recovered after HUMIRA cessation and steroid treatment. Numerous post market studies have indicated renal failure as a potential complication of HUMIRA therapy. Defendant AbbVie, Inc. did not adequately research this link or warn consumers of this risk.

PARTIES

7. Plaintiff, Marlon Bowles, is a natural person and a citizen of the State of Texas, domiciled in Texas.

8. Defendant, AbbVie, Inc. is a corporation organized and existing under the laws of Delaware, with its principal place of business at 1 North Waukegan Road, North Chicago, Lake County, Illinois 60064.

9. At all times herein mentioned, Defendant, in interstate commerce and in this judicial district, advertised, promoted, supplied and sold to distributors and retailers for resale to physicians, hospitals and medical practitioners, and marketed to the general public, the pharmaceutical

[2] *See e.g.* S. S. Wei, R. Sinniah, "Adalimumab (TNFα Inhibitor) Therapy Exacerbates IgA Glomerulonephritis Acute Renal Injury and Induces Lupus Autoantibodies in a Psoriasis Patient", *Case Reports in Nephrology*, vol. 2013, Article ID 812781, 4 pages, 2013. https://doi.org/10.1155/2013/81278; *Clinical medicine insights. Case reports* vol. 5 (2012): 13-7. doi:10.4137/CCRep.S8790; Katsanos, Konstantinos H et al. "Reversible proteinuria after adalimumab discontinuation in a patient with Crohn's disease." *NDT plus* vol. 3,1 (2010): 103-4. doi:10.1093/ndtplus/sfp158.

product HUMIRA.

JURISDICTION AND VENUE

10. This Court has jurisdiction pursuant to 28 U.S.C. 1332(a) as the parties are citizens of different States, and the amount in controversy exceeds the sum or value of $75,000.00, exclusive of interest and cost and because, among other reasons, Defendant has significant contacts with this district by virtue of doing business within this judicial district.

11. Defendant is subject to the *in personam* jurisdiction of this Court, and venue is therefore proper because the Defendant is headquartered and has its principal place of business in North Chicago, Illinois.

12. Illinois substantive law applies because the complained of conduct occurred in Illinois, giving Illinois the most significant relationship to this action. Specifically, Defendant developed, tested and marketed the subject product in Illinois, and committed acts of negligence – including unreasonable pharmacovigilance, data collection and analysis, review and response to Adverse Event and Serious Adverse Event reports – all in Illinois. Further, Defendant operated the complained of research and development, safety investigations, and regulatory analysis in Illinois.

GENERAL ALLEGATIONS

13. At all times relevant herein, Defendant was in the business of designing, testing, manufacturing, labeling, advertising, marketing, testing, promoting, selling and distributing pharmaceuticals and biologics, including HUMIRA, and other products for use by the mainstream public, including Plaintiff. The designing, testing, manufacturing, labeling, advertising, marketing, testing, promoting, selling and distributing pharmaceuticals and

biologics, including HUMIRA, all took place at or originated from the Lake Charles, Illinois location of Defendant.

14. HUMIRA was designed, manufactured, marketed, distributed and sold to the Plaintiff by Defendant, which gives rise to the causes of action and the injuries sustained as a direct and proximate result of such ingestion.

15. HUMIRA, the generic name of which is "ADALIMUMAB," is a "biologic" drug, which means that it is a medicine that has been constituted or reconstituted from natural substances in the body. It was the first such drug in its class that was derived from actual human cells. More specifically, HUMIRA is alleged to be a recombinant human IcG1 antibody that neutralizes and/or blocks the activity of the pro-inflammatory cytokine known as tumor necrosis factor ("TNF"). A cytokine is a non-antibody protein that can be made by a wide range of cell types.

16. The first authorized use or "indication" for the TNF blockers in this country was to treat rheumatoid arthritis [hereinafter "RA"]. In the treatment of RA, HUMIRA is believed to bind specifically to TNF and block its interaction with certain cell surface TNF receptors, thereby interfering with endogenous TNF activity.

17. The TNF blocker class of drugs have been heralded by some as a "miracle" treatment for rheumatoid arthritis. Undoubtedly, they do help many people. However, in the treatment of any disease with powerful medications, it is always very important for both the prescribing physician and the patient to be able to balance the potential benefits of a medication against the known risks.

18. From a financial perspective, HUMIRA has certainly been a "miracle" or "blockbuster" for Defendant. HUMIRA first received approval from the U.S. Food and Drug Administration

[FDA] on December 31, 2002 for the treatment of moderately to severely active rheumatoid arthritis. HUMIRA was launched in the United States at the beginning of 2003 and reached sales of approximately $246 million in its first year alone. By 2005, sales had reached $1.4 billion. Since that time, sales revenues have continued to grow, reaching almost $20 billion by 2018.

19. Despite its knowledge of data, reported and analyzed in Illinois, indicating that HUMIRA use is causally related to the development of serious kidney injuries and interstitial lung disease, AbbVie promoted and marketed HUMIRA as safe and effective for persons such as Plaintiff throughout the United States. The marketing of HUMIRA was developed in and distributed from Illinois.

20. As review of the publicly available adverse event information from the FDA shows that through June 30, 2015, there were more than 1,000 serious reports of the MedDRA high level term for "renal failure and impairment." There were more than 100 serious reports of the MedDRA high-level term "glomerulonephritis and nephrotic syndrome."

21. Despite the ever-increasing evidence of HUMIRA causing or contributing to serious kidney injuries, even today the package insert for HUMIRA does not contain any reference to kidney injuries.

22. At no time did Defendant seek to add warnings for kidney injuries to the package insert via Changes Being Effected as allowed under 21 C.F.R. § 314.70(c)(6)(iii)(A).

23. At no time did Defendant request via a prior approval supplement that the FDA allow Defendant to add a warning for kidney injuries, despite ever-increasing evidence concerning the relationship between HUMIRA and kidney injuries.

24. At all times material hereto, Defendant knew or should have known that the risks of HUMIRA

included severe and life-threatening kidney injuries.

25. At all times material hereto, Defendant, by and through their agents, servants, and/or employees, negligently, recklessly and/or carelessly marketed, distributed, and/or sold HUMIRA without adequate instructions or warnings of the drug's serious side effects and unreasonably dangerous risks.

26. Defendant sold or aided and abetted in the sale of HUMIRA, which was and is defective and unreasonably dangerous. At all pertinent times, Defendant knew or should have known, that HUMIRA was and is hazardous to human health.

27. Defendant, through their funding and control of certain studies concerning the effects of HUMIRA on human health, their control over trade publications, promoting, marketing, and/or through other agreements, understandings and joint undertakings and enterprises, conspired with, cooperated with and/or assisted in the wrongful suppression, active concealment and/or misrepresentation of the true relationship between HUMIRA and serious kidney injuries, to the detriment of the public health, safety and welfare.

28. Defendant, through their funding and control of certain studies concerning the effects of HUMIRA on human health, their control over trade publications, promoting, marketing, and/or through other agreements, understandings and joint undertakings and enterprises, conspired with, cooperated with and/or assisted in the wrongful suppression, active concealment and/or misrepresentation of the true relationship between HUMIRA and serious lung injuries, to the detriment of the public health, safety and welfare.

29. Specifically, and in addition to the allegations above, Defendant knew of the hazards associated with HUMIRA, affirmatively and actively concealed information which clearly demonstrated the dangers of HUMIRA, and affirmatively misled the public and prescribing physicians with

regard to the material and clear risks of HUMIRA with the intent that prescribing physicians would continue to prescribe HUMIRA. Defendant well knew that prescribing physicians would not be in a position to know the true risks of HUMIRA and Defendant knew that prescribing physicians would rely upon the misleading information that they promulgated.

30. At all pertinent times, Defendant purposefully and intentionally engaged in these activities, and continues to do so, knowing full well that when the general public, including Plaintiff, use HUMIRA as Defendant intended, they are substantially certain to suffer disease, injury, and sickness.

31. The statements, representations and promotional schemes publicized by Defendant were deceptive, false, incomplete, misleading and untrue. Defendant knew or should have known, that their statements, representations, and advertisements were deceptive, false, incomplete, misleading and untrue at the time of making such statements. Defendant had an economic interest in making such statements. Neither the Plaintiff nor the physicians who prescribed HUMIRA to them had knowledge of the falsity or untruth of Defendant's statements, representations, and advertisements when prescriptions for HUMIRA were written. Moreover, Plaintiff and Plaintiff's physicians had a right to rely on Defendant's statements, representations, and advertisements. Each of the statements, representations, and advertisements were material to the Plaintiff's purchase of HUMIRA in that the Plaintiff would not have purchased HUMIRA if Plaintiff had known that Defendant's statements, representations, and advertisements were deceptive, false, incomplete, misleading and untrue. These acts were designed to and did, in fact, allow Defendant to earn substantial income from the sale of HUMIRA.

32. Plaintiff and his health care providers had a right to rely upon the representations of Defendant

and were directly and proximately injured by such reliance, all as described above.

33. Had Plaintiff been adequately warned of the increased risk of injuries and life-threatening side effects, he would have chosen to request other prescription medications and avoided HUMIRA's injuries and potentially life-threatening side effects.

34. Even if Plaintiff and his health care professionals were willing to prescribe/inject HUMIRA, Plaintiff and his physicians would have been better able to manage and mitigate the risks of serious kidney injury had Defendant properly warned of the relationship.

35. Plaintiff was prescribed HUMIRA by a physician(s) authorized to prescribe HUMIRA, injected HUMIRA as prescribed, and as a result, suffered damages and injury.

36. Plaintiff was prescribed HUMIRA and used it as directed.

37. Plaintiff was prescribed HUMIRA to treat psoriatic arthritis.

38. Plaintiff agreed to initiate HUMIRA treatment in an effort to treat psoriatic arthritis.

39. Plaintiff developed serious kidney and lung injuries after initiating their HUMIRA treatment.

40. Defendant negligently, recklessly and wantonly failed to warn Plaintiff, Plaintiff's physicians, and the general public, of the risks associated with taking HUMIRA. Defendant failed to do so even after various studies, including their own, showed that there were problems concerning the risk of serious kidney and lung injuries associated with HUMIRA.

41. Defendant endeavored to deceive Plaintiff, and the general public, by not disclosing the findings of the various studies, including its own, that revealed problems concerning the dangers of HUMIRA.

42. Further, Defendant did not provide warnings and instructions that would have put Plaintiff and Plaintiff's physicians, and the general public, on notice of the dangers and adverse effects caused by HUMIRA.

43. In its role as the federal regulatory agency charged with overseeing pharmaceutical products, under 21 C.F.R. § 208, the FDA required that Defendant ***directly*** warn patients of risks associated with the use of HUMIRA. A "medication guide" is required to be provided to patients and provides patients with warnings, instructions, and guidance on minimizing risks associated with the use of the product.

44. In accordance with 21 C.F.R. §600.80(c), not all adverse event reports are required to be submitted to the FDA. Thus, the manufacturer will have information in its possession that is not in the possession of the FDA. Nevertheless, the manufacturer is required to review and consider all adverse event information, including that not submitted to the FDA, in accordance with 21 C.F.R. §600.80(b) as follows:

> Review of adverse experiences. Any person having a biologics license under 601.20 of this chapter must promptly review all adverse experience information pertaining to its product obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from commercial marketing experience, postmarketing clinical investigations, postmarketing epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific papers. Applicants are not required to resubmit to FDA adverse product experience reports forwarded to the applicant by FDA; applicants, however, must submit all followup information on such reports to FDA. Any person subject to the reporting requirements under paragraph (c) of this section must also develop written procedures for the surveillance, receipt, evaluation, and reporting of postmarketing adverse experiences to FDA.

45. With each Biologic Licensing Application ("BLA") and for subsequent submissions, the FDA requires that companies attach an FDA form 356h. This document, titled "Application to Market a New Drug, Biologic, Or an Antibiotic Drug for Human Use" contains a certification to be signed by the applicant. This certification contains the following language as shown in the graphic below:

CERTIFICATION

I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to, the following:

1. Good manufacturing practice regulations in 21 CFR Parts 210, 211 or applicable regulations, Parts 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR Part 202.
5. Regulations on making changes in application in FD&C Act section 506A, 21 CFR 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80, and 600.81.
7. Local, state, and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information in this submission have been reviewed and, to the best of my knowledge, are certified to be true and accurate.

Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

46. Absent the inclusion of form 356h, the FDA will not accept the submission. Furthermore, with each submission to the FDA, a new 356h is signed and attached as the cover to the submission.

47. On information and belief, Defendant attached and signed such a document with the HUMIRA BLA and with each submission to the BLA going forward continuing until the present time. HUMIRA was ultimately approved by the FDA. As part of the certification, Defendant represented that they would update the application with new information that could affect the statement of contraindications, warnings, precautions or adverse events. Defendant negligently failed to update statement of contraindications, warnings, precautions, and adverse reactions that Defendant affirmatively knew about; as set forth in this Complaint.

48. Although the application for HUMIRA was approved and marketing commenced, Defendant negligently failed to comply with various regulations including, but not limited to, 21 C.F.R. § 201, 21 C.F.R. § 202, 21 C.F.R. § 600.80, and 21 C.F.R. § 600.81.

49. As set forth more fully in the counts for Negligence and Strict Liability- Failure to Warn, these regulations all relate to monitoring the safety of HUMIRA and labeling changes required to properly inform Plaintiff and Plaintiff's health care professionals. Because Defendant failed

to properly monitor the safety of HUMIRA as required under 21 C.F.R. § 600.80 the label for HUMIRA was never properly updated as required by 21 C.F.R. § 201.57.

50. Compliance with these regulations was a condition precedent of approval of HUMIRA. As such, the drug and its labeling were not in compliance with the United States Food and Drug Administration's approval at the time the drug left the control of the Defendant and ultimately administered to the Plaintiff.

51. The purpose of the safety surveillance regulations 21 C.F.R. § 600.80 and the labeling regulations 21 C.F.R. § 201.57 is to ensure that Plaintiff and Plaintiff's health care professionals were provided relevant safety information concerning HUMIRA. Any failure to comply with these regulations directly affected Plaintiff.

52. At all times, Defendant possessed more information than the FDA concerning the relationship between HUMIRA and injuries like those suffered by Plaintiff.

53. Interstitial lung disease was not included in the launch labeling for HUMIRA in 2002.

54. No later than September 27, 2005, interstitial lung disease was added to the spontaneous reporting adverse event section of the label- the least important section of the label for indicating possible risks.

55. Once interstitial lung disease was added to the label, no foreign adverse event reports for interstitial lung disease would be reported to the FDA in accordance with 21 § C.F.R. 600.80(c)(2)(iii). Thus, Defendant had adverse event information in their possession that was not shared with the FDA.

56. Although the above foreign interstitial lung disease reports would not need to be shared with the FDA, they are material, and Defendant was required to review and consider this information in accordance with 21 C.F.R. § 600.80(b).

57. Worldwide, regulatory agencies, including the FDA and the Pharmaceutical industry, including Defendant, use a standardized method to classify adverse events known as MedDRA.

58. One component of MedDRA is a concept of Standard MedDRA Queries ("SMQ"). These SMQs are employed to collect adverse event terms associated with specific conditions. Experts in the field create the SMQs.

59. There is an SMQ for interstitial lung disease.

60. A review of the publicly available adverse event data from the FDA shows that as of June 30, 2015, there were 764 serious reports of reports under the SMQ for interstitial lung disease. In assessing that number, the following conditions were employed: (1) the narrow scope term definition of the SMQ, (2) HUMIRA was prescribed without any of the following drugs: Enbrel, Remicade, or Arava, (3) there was at least one serious criteria besides "other medically important." These conditions substantially limit the number of actual reports, and a more relaxed definition would lead to many more reports.

61. The vast bulk of the 764 reports were reported to the FDA by Defendant. Because these are only the reports sent to the FDA and exclude most foreign interstitial lung disease reports, the counts are likely to be far higher as known to Defendant and ***not the FDA***.

62. The FDA routinely considers safety information for HUMIRA, Enbrel, and Remicade together. Doing so here shows 2,893 reports for the SQM for interstitial lung disease.

63. Thus, as of the time Plaintiff injected HUMIRA, Defendants were aware of numerous reports of kidney and lung related injuries.

64. Given the large number of adverse event reports received by Defendant, internal information only in the possession of Defendant, and the reasonably available scientific literature

Defendant knew or should have known that the label as of Plaintiff's injection was inadequate with respect to the relationship between HUMIRA and Plaintiff's injuries.

65. At no time did Defendant change the label with respect to kidney or lung injury nor did they petition the FDA for the inclusion of kidney or lung injury in the label.

66. The kidney and lung injuries observed by Defendant were clinically significant and potentially fatal and constituted a significant hazard. Defendant knew or should that there was reasonable evidence of a causal association between HUMIRA and the same injuries as suffered by Plaintiff before Plaintiff ingested HUMIRA.

67. As such, kidney and lung injuries were required to be added to the warnings section of the package insert in accordance with 21 C.F.R. § 201.57(c)(6). Defendant failed to update the label for kidney and lung injuries.

68. The package insert for HUMRIA was written by Defendant who had primary responsibility for its content. The purpose of the package insert is to advise health care professionals and patients of the risks associated with the use of HUMIRA.

69. By failing to update the label, patients such as Plaintiff and his health care professionals were not made aware by Defendant of the true risks associated with HUMIRA.

70. Defendant was not required to submit ***all*** safety information to the FDA, but was required to review and consider all safety related information in assessing whether an update to the HUMRIA label was required.

71. Defendant failed to review and consider all safety related information concerning kidney and lung related injuries as suffer by Plaintiff.

72. The FDA required that Defendant create a medication guide for HUMIRA because FDA determined that the use of HUMRIA poses a serious and significant public health concern requiring distribution of FDA-approved patient information.

73. The medication guide for HUMRIA is a specific document created for the patient that is to be delivered to the patient by the health care professional or the pharmacy in which they receive the drug.

74. The purpose of patient labeling for human prescription drug products is to provide information when the FDA determines in writing that it is necessary to patients' safe and effective use of drug products.

75. With respect to HUMIRA, the FDA determined that one or more of the following circumstances exist:

    a. The drug product is one for which patient labeling could help prevent serious adverse effects.

    b. The drug product is one that has serious risk(s) (relative to benefits) of which patients should be made aware because information concerning the risk(s) could affect patients' decision to use, or to continue to use, the product.

    c. The drug product is important to health and patient adherence to directions for use is crucial to the drug's effectiveness.

76. Thus, the FDA determined that there are specific warnings and instructions for use to be given directly to the patient.

77. Defendant failed to include warnings for kidney and lung injuries in the Medication Guide.

SPECIFIC FACTUAL ALLEGATIONS

78. Plaintiff Marlon Bowles was a 51-year-old male whose life has been catastrophically affected as a result of the subcutaneous HUMIRA injections he was prescribed and received between March 8, 2018 and April 27, 2018.

79. Mr. Bowles was prescribed HUMIRA ostensibly to treat his psoriatic arthritis. He received a total of three doses of HUMIRA via subcutaneous injection.

80. On April 27, 2018, he began experiencing left foot swelling and shortness of breath. Plaintiff went to the emergency room where he was immediately hospitalized and underwent hemodialysis. During his hospitalization, Mr. Bowles developed Mycobacterium abscessus complex infection and E-coli bacteremia.

81. Plaintiff was diagnosed with acute renal failure secondary minimal change disease, nephrotic syndrome secondary to minimal change disease, acute glomerulonephritis, acute congestive heart failure due to volume overload, and interstitial lung disease.

82. Plaintiff continues to have persistent shortness of breath and intermittent productive cough. He is unable to ambulate for long distances due to shortness of breath. He has faced numerous restrictions in his functional activities and has required assistance for activities of his daily living. Mr. Bowles also suffers from difficulty sleeping due to cough and dyspnea. He is prone to acquire infection as he is now immuno-suppressed and has had to be hospitalized multiple times for receiving intravenous antibiotics. Mr. Bowles faces possible hemodialysis in the future. Mr. Bowles has also been diagnosed with progressive interstitial lung disease of usual interstitial pneumonitis (UIP) type, a serious condition which if life threatening. The only current life-saving treatment for UIP interstitial lung disease is a lung transplant.

83. Before he started HUMIRA, Mr. Bowles had no diagnosis of kidney problems or chronic

progressive interstitial lung disease. He was diagnosed with both within a few weeks of receiving his HUMIRA injections for psoriatic arthritis. The absence of these illnesses prior to starting HUMIRA and his treating rheumatologist and pulmonologist stating that his subsequent hospitalization and treatment was caused by HUMIRA establish that his subsequent conditions were caused by HUMIRA. On April 30, 2018 Dr. Jayasree Grandhi, M.D. specializing in nephrology reviewed the kidney biopsy report of Plaintiff after he suffered renal failure and stated it revealed "minimal change disease with [acute tubular necrosis] likely related to Humira." On June 13, 2018, Dr. Anthony Ortegon, M.D., a pulmonary specialist, stated that "Mr. Bowles had an active autoimmune process with interstitial lung disease. He also had evidence of a fibrotic lung injury that was suggestive of a protracted inflammatory process." Dr. Ortegon further stated "Mr. Bowles' acute kidney injury was a complication of subcutaneous Humira injections."

84. The medication guide for HUMRIA did not include warnings of kidney and lung disease as suffered by Plaintiff.

85. As a foreseeable, direct, and proximate result of AbbVie's conduct described herein, Marlon Bowles has suffered damages, including lost wages, pain and suffering, lasting injury, mental anxiety and anguish, and medical bills in amounts to be proven at trial.

FIRST CAUSE OF ACTION
STRICT LIABILITY—FAILURE TO WARN

86. Plaintiff incorporates by reference herein each of the allegations heretofore set forth in this Complaint as though fully set forth herein

87. The HUMIRA manufactured and/or supplied by Defendant was defective due to inadequate warnings or instructions because Defendant knew or should have known that the products created significant risks of serious bodily harm to consumers, and they failed to adequately

warn consumers and/or their health care providers of such risks. The HUMIRA manufactured and/or supplied by Defendant was defective due to inadequate post-marketing warnings or instructions because, after Defendant knew or should have known of the risk of serious bodily harm from the use of HUMIRA, Defendant failed to provide an adequate warning to consumers and/or their health care providers of the product, knowing the products could cause serious injury.

88. As a direct and proximate result of Plaintiff reasonably anticipated use of HUMIRA as manufactured, designed, sold, supplied, marketed and/or introduced into the stream of commerce by Defendant, Plaintiff suffered serious injury, harm, damages, economic and non-economic loss and will continue to suffer such harm, damages and losses in the future.

SECOND CAUSE OF ACTION
NEGLIGENCE

89. Plaintiff incorporates by reference herein each of the allegations set forth in this Complaint as though set forth herein.

90. Defendant directly or indirectly caused HUMIRA, to be sold, distributed, packaged, labeled, marketed, promoted, and/or used by Plaintiff.

91. At all times herein mentioned, Defendant had a duty to properly manufacture, design, formulate, compound, test, produce, process, assemble, inspect, research, distribute, market, label, package, prepare for use, sell, prescribe and adequately warn of the risks and dangers of HUMIRA, including the duty to take all reasonable steps necessary to ensure their drugs were not unreasonably dangerous to its consumers and users.

92. At all times herein mentioned, Defendant negligently and carelessly manufactured, designed, formulated, distributed, compounded, produced, processed, assembled, inspected, distributed, marketed, labeled, packaged, prepared for use and sold HUMIRA.

93. At all times herein mentioned, Defendant failed to adequately test and warn of the risks and dangers of HUMIRA.

94. At all times material hereto, Defendant had actual knowledge, or, in the alternative, should have known through the exercise of reasonable and prudent care, of the hazards and dangers associated with the use of HUMIRA. Specifically, as alleged above, Defendant knew or should have known of the risks of severe kidney and lung injury associated with the use of HUMIRA prior to Plaintiff's injection of HUMIRA and subsequent injury.

95. Defendant had a duty to test HUMIRA to determine the hazards and dangers associated with HUMIRA, especially as it related to severe kidney and lung injury.

96. Defendant had a duty to disclose to health care professionals the causal relationship or association of HUMIRA to the development of Plaintiff's injuries.

97. Defendant's duty of care owed to consumers, health care professionals, and patients included providing (1) accurate information concerning the clinical safety and effectiveness profiles of HUMIRA, and (2) appropriate, complete, and accurate warnings concerning the adverse effects of HUMIRA, including the injuries suffered by Plaintiff.

98. During the time that Defendant designed, manufactured, packaged, labeled, promoted, distributed, and/or sold HUMIRA, it knew, or in the exercise of reasonable care should have known, that its products were defective, dangerous, and otherwise harmful to Plaintiff as described above herein.

99. Defendant knew, or in the exercise of reasonable care should have known, that the use of HUMIRA could cause or be associated with Plaintiff's injuries, namely the development of serious kidney and lung injury, and thus created a dangerous and unreasonable risk of injury to users of the products.

100. Defendant knew that many health care professionals were prescribing HUMIRA, and that many patients developed serious side effects including severe kidney injuries.

101. Despite this knowledge, as outlined herein, Defendant did not perform additional testing or include any warnings of the risk of kidney injury associated with HUMIRA in its warning labels, television advertising, marketing materials, or sales representative statement to doctors. Instead, the messaging was that HUMIRA were safe and effective.

102. Defendant breached its duty of reasonable care and failed to exercise ordinary care in the design, research, development, manufacture, marketing, supplying, promotion, marketing, advertisement, packaging, sale, testing, quality assurance, quality control, sale, and distribution of HUMIRA in interstate commerce, in that the Defendant knew and had reason to know that a consumer's use and injection of HUMIRA created a significant risk of suffering unreasonably dangerous health related side effects, including Plaintiff's injuries, and failed to prevent or adequately warn of the severity of these risks and injuries.

103. Defendant was further negligent in that it manufactured and produced a defective product and knew and was aware of the defects inherent in its products, failed to act in a reasonably prudent manner in designing, testing, and marketing their product, and failed to provide adequate warnings of their product's defects and risks.

104. Defendant failed to exercise due care under the circumstances, and their negligence includes the following acts and omissions:

a. failing to properly and thoroughly test HUMIRA before releasing the drugs to market;

b. failing to properly and thoroughly analyze the data resulting from the pre- marketing tests of HUMIRA;

c. failing to conduct sufficient post-market testing and surveillance of HUMIRA;

d. designing, manufacturing, marketing, advertising, distributing, and selling HUMIRA to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of the medication and without proper instructions to avoid foreseeable harm;

e. failing to accompany its product with proper or adequate warnings or labeling regarding adverse side effects and health risks associated with the use of HUMIRA and the comparative severity of such adverse effects;

f. failing to provide warnings, instructions or other information that accurately reflected the symptoms, scope, and severity of the side effects and health risks, including but not limited to those associated with the severity of HUMIRA's effect on renal function;

g. failing to adequately warn users, consumers, and physicians about the need to monitor renal function in patients that do not already suffer from renal impairment;

h. failing to adequately warn treating emergency personnel and family doctors and internists of the risks and the need to discontinue the use of the medications;

i. failing to exercise due care when advertising and promoting HUMIRA; and

j. negligently continuing to manufacture, market, advertise, and distribute HUMIRA after it knew or should have known of the adverse effects.

105. Defendant had a duty to create a product that was not unreasonably dangerous for its normal, common, and intended use.

106. Defendant negligently and carelessly breached this duty of care to Plaintiff because HUMIRA was and is unreasonably defective in design as follows:

a. HUMIRA is not reasonably safe as intended to be used;

b. HUMIRA is more dangerous than an ordinary consumer would expect and more

dangerous than other risks associated with like products;

c. HUMIRA's package insert contained insufficient, incorrect, and defective warnings in that they failed to alert health care professionals and users, including Plaintiff, of the severity of the risks of adverse effects;

d. HUMIRA was not safe for its intended use;

e. HUMIRA was not adequately tested;

f. HUMIRA's risks exceeded any benefit of the drugs;

107. Defendant knew and/or should have known that it was foreseeable that consumers such as Plaintiff would suffer injuries as a result of the Defendant's failure to exercise ordinary care in the manufacturing, marketing, labeling, distribution and sale of HUMIRA.

108. Plaintiff did not know the nature and extent of the injuries that could result from injection and use of HUMIRA.

109. Defendant's negligence was the proximate cause of the injuries, harm, and economic losses that Plaintiff suffered, and will continue to suffer, as described herein.

110. Defendant's conduct, as described above, was reckless. The Defendant's actions and inaction risked the lives of consumers and users of their product, including Plaintiff.

111. Defendant's HUMIRA was expected to, and did, reach the intended consumers, handlers and persons coming into contact with the drug without substantial change in the condition in which it was researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendant.

112. At all times relevant hereto, HUMIRA were manufactured, designed and labeled in an unsafe, defective and inherently dangerous condition, which were dangerous for use by the public and in particular by Plaintiff.

113. Plaintiff used HUMIRA for their intended purposes and in a manner normally intended: to treat psoriatic arthritis.

114. The harm caused by HUMIRA, namely Plaintiff's development of serious kidney and lung injury, far outweighed the benefits, rendering HUMIRA more dangerous and less effective than an ordinary consumer or health care professionals would expect and more dangerous than alternative products. Defendant could have designed HUMIRA, to make them less dangerous. When the defendant manufactured HUMIRA, the state of the industry's scientific knowledge was such that a less risky design was attainable.

115. At the time HUMIRA left Defendant's control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of HUMIRA.

116. Defendant had an ongoing duty of pharmacovigilance. As part of this duty, Defendant is required to continually monitor, test, and analyze data regarding the safety, efficacy, and prescribing practices of its marketed drugs, including HUMIRA. Defendant continually received reports from its own clinical trials, practicing physicians, individual patients and regulatory authorities concerning adverse events that occur in patients taking HUMIRA and Defendant's other marketed drugs. Furthermore, Defendant continued to conduct clinical trials for its marketed drugs long after the drug is approved for use. Defendant had a continuing duty to inform doctors, regulatory agencies, and the public of new safety and efficacy information they learn, or should have learned, about their marketed drugs once that information becomes available to Defendant, whether through Defendant's clinical trials, other outside sources or pharmacovigilance activities. Specifically, when Defendant learned or should have learned of new safety information associated with its marketed drugs, Defendant had a duty to promptly

disseminate that data to the public. Defendant also had a continuing duty to monitor epidemiology and pharmacovigilance data regarding its marketed drugs and promptly report any safety concerns that arise through epidemiologic study or data.

117. Defendant was further negligent and breached this continuing duty of pharmacovigilance with respect to Plaintiff. Defendant, through clinical trials and other adverse event reports, learned that there was a serious problem associated with HUMIRA's use and failed to adequately inform doctors, regulatory agencies and the public of this risk. Defendant had the means and the resources to perform its pharmacovigilance duties for the entire time HUMIRA has been on the market in the United States. Furthermore, Defendant had a duty to provide adequate instructions to manage or mitigate the known risks associated with the use of HUMIRA and failed to so instruct.

118. Defendant failed to comply with the FDA post-marketing reporting requirements under 21 C.F.R. § 314.80(c) by, inter alia, failing to report each adverse drug experience concerning HUMIRA that is both serious and unexpected, whether foreign or domestic, as soon as possible but in no case later than 15 calendar days after initial receipt of the information by defendant, failing to promptly investigate all adverse drug experiences concerning HUMIRA that are the subject of these post-marketing 15-day Alert reports, failing to submit follow-up reports within 15 calendar days of receipt of new information or as requested by FDA, and, if additional information was not obtainable, failing to maintain records of the unsuccessful steps taken to seek additional information. Defendant further failed to meet the periodic reporting requirements of 21 C.F.R. § 314(c), 21 C.F.R. § 314.81, and 21 C.F.R. § 312.33.

119. Defendant failed to develop and act upon written procedures for the surveillance, receipt, evaluation, and reporting of post-marketing adverse drug experiences to FDA.

120. Defendant failed to adequately instruct doctors on patients on risk mitigation concerning infections associated with the use of HUMIRA.

121. Despite the availability of publicly available adverse event information from the FDA, Defendant failed to make adequate use of this information including information on the relationship between other TNF inhibitors and infections. Defendant failed to promptly review all adverse drug experience information concerning the risk of infections associated with the use of HUMIRA.

122. Defendant's failure to perform adequate pharmacovigilance and failure to comply with the post-marketing requirements of FDA regulations is evidence of Defendant's negligence.

123. Had Defendant properly conducted pharmacovigilance as required, the totality of the information available, much of which was in the exclusive possession of Defendant, would have shown that the risks of diabetes through the use of HUMIRA warranted the inclusion of a warning ion the package insert.

124. Despite the fact that Defendant knew or should have known that HUMIRA caused unreasonable, dangerous side effects, Defendant continued to market HUMIRA to consumers including Plaintiff, when there were safer alternative methods of treating psoriatic arthritis.

125. Plaintiff could not, in the reasonable exercise of care, have discovered the defects of HUMIRA and perceived the danger.

126. The defects in HUMIRA were substantial contributing factors in causing Plaintiff's injuries. But for the defendant's acts and omissions, Plaintiff would not have suffered the injuries complained of herein.

127. As a foreseeable, direct, and proximate consequence of Defendant's actions, omissions, and misrepresentations, Plaintiff suffered acute renal failure, acute glomerulonephritis, acute

congestive heart failure due to volume overload, Nephrotic syndrome, interstitial lung disease, and other related health complications. In addition, as a result of the injuries caused by Defendant, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

THIRD CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY

128. Plaintiff incorporates by reference here each of the allegations heretofore set forth in this Complaint as though fully set forth herein.

129. Prior to the time that the aforementioned products were used by Plaintiff, Defendant impliedly warranted to Plaintiff and Plaintiff's agents and physicians that HUMIRA was of merchantable quality and safe and fit for the use for which it was intended.

130. Plaintiff was and is unskilled in the research, design and manufacture of the products and reasonably relied entirely on the skill, judgment and implied warranty of the Defendant in using HUMIRA.

131. HUMIRA was neither safe for its intended use nor of merchantable quality, as warranted by Defendant, in that HUMIRA has dangerous propensities when used as intended and will cause severe injuries to users.

132. As a result of the abovementioned breach of implied warranties by Defendant, Plaintiff suffered injuries and damages as alleged herein.

FOURTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY

133. Plaintiff incorporates by reference here each of the allegations set forth in this Complaint as though fully set forth here.

134. At all times mentioned, Defendant expressly represented and warranted to Plaintiff and Plaintiff's agents and physicians, by and through statements made by Defendant or its authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that HUMIRA is safe, effective, fit and proper for its intended use. Plaintiff purchased HUMIRA relying upon these warranties.

135. In utilizing HUMIRA, Plaintiff relied on the skill, judgement, representations, and foregoing express warranties of Defendant. These warranties and representations were false in that HUMIRA is unsafe and unfit for its intended uses.

136. As a result of the above-mentioned breach of express warranties by Defendant, Plaintiff suffered injuries and damages as alleged herein.

FIFTH CAUSE OF ACTION
FRAUD

137. Plaintiff incorporates by reference here each of the allegations set forth in this Complaint as though set forth fully herein.

138. Defendant, from the time they first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed HUMIRA, and up to the present, willfully deceived Plaintiff by concealing from him, Plaintiff's physicians and the general public, the true facts concerning HUMIRA, which the Defendant had a duty to disclose.

139. At all times herein mentioned, Defendant conducted a sales and marketing campaign to promote the sale of HUMIRA and willfully deceived Plaintiff, Plaintiff's physicians and the general public as to the benefits, health risks and consequences of using HUMIRA. Defendant knew of the foregoing, that HUMIRA is not safe, fit and effective for human consumption, that using HUMIRA is hazardous to health, and that HUMIRA has a serious propensity to cause serious injuries to its users, including but not limited to the injuries Plaintiff suffered.

140. Defendant concealed and suppressed the true facts concerning HUMIRA with the intent to defraud Plaintiff, in that Defendant knew that Plaintiff physicians would not prescribe HUMIRA, and Plaintiff would not have used HUMIRA, if he were aware of the true facts concerning its dangers.

141. As a result of Defendant's fraudulent and deceitful conduct, Plaintiff suffered injuries and damages as alleged herein.

SIXTH CAUSE OF ACTION
NEGLIGENT FAILURE TO TEST

142. Plaintiff incorporates by reference herein each of the allegations set forth in the complaint as though fully set forth herein.

143. Defendant has a duty to adequately test its products to ensure that their drugs are not unreasonably dangerous to its consumers and users.

144. At all times material hereto, Defendant had actual knowledge, or, in the alternative, should have known through the exercise of reasonable and prudent care, of the hazards and dangers associated with the use of HUMIRA.

145. As alleged above, Defendant knew or should have known of the risks of severe kidney and lung injury associated with the use of HUMIRA prior to Plaintiff's injection of HUMIRA and subsequent injury. Specifically, at all times material hereto, Defendant had notice of

HUMIRA's propensity to cause kidney injury and interstitial lung disease through Adverse Event reports, case studies, and other reporting and/or research.

146. Despite being on notice of these known risks, Defendant failed to perform reasonable testing of HUMIRA's link to kidney injury and interstitial lung disease, all the while continuing to place HUMIRA in the stream of commerce.

147. Defendant could have performed reasonable testing of HUMIRA in regards to its risk of causing kidney injury and interstitial lung disease. The failure to do so deprived consumers, including Plaintiff, of a reasonably safe product.

148. Defendant's willful blindness caused Plaintiff to unknowingly take a product that was not reasonably and adequately tested for known risks and, therefore, was not reasonable safe.

149. As a result of the foregoing negligent misrepresentations by Defendant, Plaintiff suffered injuries and damages as alleged herein.

SEVENTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

150. Plaintiff incorporates by reference herein each of the allegations set forth in this Complaint as though fully set forth herein.

151. From the time HUMIRA was first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, Defendant made misrepresentations to Plaintiff, Plaintiff's physicians and the general public, including but not limited to the misrepresentation that HUMIRA was safe, fit and effective for human consumption. At all times mentioned, Defendant conducted sales and marketing campaigns to promote the sale of HUMIRA and willfully deceive Plaintiff, Plaintiff's physicians and the general public as to the health risks and consequences of the use of the above-mentioned product.

152. The Defendant made representations regarding the safety of HUMIRA without any reasonable ground for believing them to be true. These representations were made directly by Defendant, by sales representatives and other authorized agents of Defendant, and in publications and other written materials directed to physicians, medical patients and the public, with the intention of inducing reliance and the prescription, purchase and use of the subject product.

153. The representations by the Defendant were in fact false, in that HUMIRA is not safe, fit and effective for human consumption. Using HUMIRA is hazardous to health, and HUMIRA has a serious propensity to cause serious injuries to users, including but not limited to the injuries suffered by Plaintiff.

154. The foregoing representations by Defendant, and each of them, were made with the intention of inducing reliance and the prescription, purchase and use of HUMIRA.

155. In reliance of the misrepresentations by the Defendant, and each of them, Plaintiff was induced to purchase and use HUMIRA. If Plaintiff had known of the true facts and the facts concealed by the Defendant, Plaintiff would not have used HUMIRA. The reliance of Plaintiff upon Defendant's misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know the true facts.

156. As a result of the foregoing negligent misrepresentations by Defendant, Plaintiff suffered injuries and damages as alleged herein.

EIGHTH CAUSE OF ACTION
GROSS NEGLIGENCE

157. Plaintiff incorporates by reference herein each of the allegations set forth in this Complaint as though fully set forth herein.

158. The wrongs done by Defendant were aggravated by malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff, in that the Defendant's conduct

was specifically intended to cause substantial injury to Plaintiff. When viewed objectively from Defendant's standpoint at the time of the conduct, considering the probability and magnitude of the potential harm to others, the Defendant's conduct involved an extreme degree of risk.

159. Defendant was actually and subjectively aware of the risk involved, but nevertheless proceeded with complete indifference to or a conscious disregard for to the rights, safety, or welfare of others. Moreover, Defendant made material representations that were false, with actual knowledge of or reckless disregard for their falsity, with the intent that the representations be acted on by Plaintiff and Plaintiff's healthcare providers.

160. Plaintiff relied on Defendant's representations and suffered injuries as a proximate result of this reliance.

161. Plaintiff also alleges that the acts and omissions of Defendant, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiff.

162. Plaintiff is entitled to an award of punitive and exemplary damages based upon Defendant's intentional, willful, knowing, fraudulent, and malicious acts, omissions, and conduct, and the Defendant's reckless disregard for the public safety and welfare. Defendant intentionally and fraudulently misrepresented facts and information to both the medical community and the general public, including Plaintiff, by making intentionally false and fraudulent misrepresentations about the safety of HUMIRA. Defendant intentionally concealed the true facts and information regarding the serious risks of harm associated with the injection of HUMIRA, and intentionally downplayed the type, nature, and extent of the adverse side effects

of injecting HUMIRA, despite their knowledge and awareness of these serious side effects and risks.

163. Defendant had knowledge of, and were in possession of evidence demonstrating that HUMIRA caused serious side effects, including kidney injury. Notwithstanding their knowledge, Defendant continued to market HUMIRA by providing false and misleading information with regard to their product's safety to the medical community, and consumers of HUMIRA.

164. Although Defendant knew or recklessly disregarded the fact that HUMIRA caused debilitating and potentially lethal side effects, Defendant continued to market, promote, and distribute HUMIRA to consumers, including Plaintiff, without disclosing these side effects when there were safer alternative methods for psoriatic arthritis.

165. Defendant failed to provide adequate warnings that would have dissuaded healthcare professionals from prescribing HUMIRA and consumers from purchasing and injecting HUMIRA, thus depriving both from weighing the true risks against the benefits of prescribing, purchasing, or consuming HUMIRA.

166. Defendant knew of HUMIRA's defective nature as set forth herein, but continued to design, manufacture, market, distribute, sell, and/or promote the drugs to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in a conscious, reckless, or negligent disregard of the foreseeable harm caused by HUMIRA.

167. Defendant's acts, conduct, and omissions were willful and malicious. Defendant committed these acts with knowing, conscious, and deliberate disregard for the rights, health, and safety of Plaintiff and other users of HUMIRA and for the primary purpose of increasing Defendant's profits from the sale and distribution of HUMIRA. Defendant's outrageous and

unconscionable conduct warrants an award of exemplary and punitive damages against Defendant in an amount appropriate to punish and make an example.

168. Prior to the manufacture, sale, and distribution of HUMIRA, Defendant knew that HUMIRA was in a defective condition and knew that those who were prescribed the medications would experience and did experience severe physical, mental, and emotional injuries. Further, Defendant, through its officers, directors, managers, and agents, knew that HUMIRA presented a substantial and unreasonable risk of harm to the public, including Plaintiff. As such, Defendant unreasonably subjected consumers of HUMIRA to risk of injury.

169. Despite their knowledge, Defendant, acting through their officers, directors and managing agents, for the purpose of enhancing the Defendant's profits, knowingly and deliberately failed to remedy the known defects in HUMIRA and failed to adequately warn the public, including Plaintiff, of the extreme risk of injury occasioned by said defects. Defendant and their respective agents, officers, and directors intentionally proceeded with the manufacturing, sale, distribution, and marketing of HUMIRA knowing these actions would expose persons to serious danger in order to advance the Defendant's pecuniary interest and monetary profits.

170. Defendant's conduct was committed with willful and conscious disregard for the safety of Plaintiff, entitling Plaintiff to exemplary damages.

DAMAGES

171. Plaintiff is seeking the following actual damages which are proximately caused by Defendants' wrongful conduct:

a. Past and future medical treatment;

b. Past and future mental anguish;

c. Past and future physical limitations;

d. Past and future pain and suffering;

e. Past and future physical scarring;

f. Lost wages and wage-earning capacity; and

g. Past and future loss of enjoyment of life.

PUNITIVE DAMAGES ALLEGATIONS

172. Plaintiff incorporates by reference here each of the allegations set forth in this Complaint as though fully set forth herein.

173. The acts, conduct, and omissions of Defendant, as alleged throughout this Complaint were willful and malicious. Defendant committed these acts with a conscious disregard for the rights of Plaintiff and other HUMIRA users and for the primary purpose of increasing Defendant's profits from the sale and distribution of HUMIRA. Defendant's outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against Defendant in an amount appropriate to punish and make an example of Defendant.

174. Prior to the manufacturing, sale, and distribution of HUMIRA, Defendant knew that said medication was in a defective condition as previously described herein and knew that those who were prescribed the medication would experience and did experience severe physical, mental, and emotional injuries. Further, Defendant, through their officers, directors, managers, and agents, knew that the medication presented a substantial and unreasonable risk of harm to the public, including Plaintiff and as such, Defendant unreasonably subjected consumers of said drugs to risk of injury or death from using HUMIRA.

175. Despite its knowledge, Defendant, acting through its officers, directors and managing agents for the purpose of enhancing Defendant's profits, knowingly and deliberately failed to remedy the known defects in HUMIRA and failed to warn the public, including Plaintiff, of the extreme

risk of injury occasioned by said defects inherent in HUMIRA. Defendant and its agents, officers, and directors intentionally proceeded with the manufacturing, sale, and distribution and marketing of HUMIRA knowing these actions would expose persons to serious danger in order to advance Defendant's pecuniary interest and monetary profits.

176. Defendant's conduct was despicable and so contemptible that it would be looked down upon and despised by ordinary decent people, and was carried on by Defendant with willful and conscious disregard for the safety of Plaintiff, entitling Plaintiff to exemplary damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against the Defendant, as follows, appropriate to each cause of action alleged and as appropriate to the particular standing of Plaintiff:

i. General damages in an amount that will conform to proof at time of trial;

ii. Special damages in an amount within the jurisdiction of this Court and according to proof at the time of trial;

iii. Loss of earnings and impaired earning capacity according to proof at the time of trial;

iv. Medical expenses, past and future, according to proof at the time of trial:

v. For past and future mental and emotional distress, according to proof;

vi. Damages for loss of care, comfort, society, and companionship in an amount within the jurisdiction of this Court and according to proof;

vii. For punitive or exemplary damages according to proof;

viii. Restitution, disgorgement of profits, and other equitable relief;

ix. Injunctive relief;

x. Attorney's fees;

xi. For costs of suit incurred herein;

xii. For pre-judgment interest as provided by law; and

xiii. For such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a jury trial on all claims so triable in this action.

RESPECTFULLY SUBMITTED,

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